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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GARCIA, MAURIE E

ART UNIT PAPER NUMBER

1627

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/756,092

Applicant(s)
Cima et al

Examiner
Maurie E. Garcia, Ph. D.

Art Unit
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-169 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-169 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Supervisory Patent Examiner, at (703) 308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-21, drawn to an array of samples, each sample comprising a compound-of-interest, classified in various places depending on the identity of the compound, for example, any of class 424 or 514 or 540-570; or class 435, DIG 34.
 - II. Claims 22-38, drawn to a method of preparing an array, classified in various places depending on the samples in the array, for example, any of class 424 or 514 or 540-570; or class 435, DIG 46.
 - III. Claims 39-59, drawn to a method of screening a plurality of solid-forms of a compound-of-interest, classified in various places depending on the identity of the compound, for example, class 436, subclass 501+ or class 435, subclasses 4-7.2 or class 424, subclasses 400+.
 - IV. Claims 60-85, drawn to a method of identifying optimal solid-forms of a compound-of-interest, classified in various places depending on the identity of the compound and method of identification, for example, any of class 422 or 424 or 435 or 436; e.g. class 424, subclasses 464-483.
 - V. Claims 86-103, drawn to a method to determine sets of conditions and/or components to produce particular solid-forms of a compound-of interest, classified in various places depending on the identity of the compound and particular conditions and/or components, for example, any of class 422 or 435 or 436; e.g. class 422, subclasses 245.1-254.

- VI. Claims 104-117, drawn to a method of screening conditions and/or components for compatibility with one or more selected solid-forms of a compound-of-interest, classified in various places depending on the identity of the compounds and particular conditions and/or components, for example, any of class 422 or 435 or 436.
 - VII. Claims 118-127, drawn to a system to identify optimal solid-forms, classified in various places depending on the interaction tested, for example, class 435, subclasses 287.1-288.7.
 - VIII. Claims 128-140, drawn to a method to determine a set of processing parameters and/or components to inhibit the formation of a solid-form of a compound-of-interest, classified in various places depending on the identity of the compound and particular parameters and/or components, for example, any of class 422 or 435 or 436; e.g. class 435, subclasses 286.1-286.7.
 - IX. Claims 141-152, drawn to a method to determine a set of processing parameters and/or components to dissolve or partially dissolve a solid-form of a compound-of-interest, classified in various places depending on the identity of the compound and particular parameters and/or components, for example, any of class 422 or 435 or 436; e.g. class 422, subclasses 255-290.
 - X. Claims 153-169, drawn to a method for determining conditions and/or components which produce a compound-of-interest or a diastereomeric derivative thereof in stereomerically enriched or conglomerate form, classified in various places depending on the identity of the compound and particular conditions and/or components, for example, any of class 422 or 435 or 436.
2. Note that the classification of Groups I-X above has been set forth in very general terms. It is impossible to particularly classify each of the groups due to the fact that the groups encompass an enormous variety of different "compounds", "components", "conditions" and/or "parameters" of undefined structure or function. See also paragraph 13 below.
3. The inventions are distinct, each from the other because of the following reasons:

4. Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the array of Group I could be made by a different process than that of Group II. For example, the array could be made by sequential synthesis (instead of parallel) or synthesized on the basis of a computer simulation.

5. Groups I and Groups III, IV, V & IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the array of the instant Group I can be used in a substantially different process; i.e. used as a starting material for synthesis of further arrays.

6. Groups I and Groups VI, VIII & X are not related as the array used in the methods of Groups VI, VIII & X is not the same as the array claimed in Group I. For example, in Group VI, the array comprises samples comprising the compound-of-interest in solid or dissolved form. In Group VIII, the array comprises samples comprising a solution of the compound-of-interest. In Group X, the array comprises samples comprising the compound-of-interest or a diastereomeric derivative thereof. These arrays are different

from that in Group I and thus the methods are deemed to not be related to Group I. However, if applicant were to argue that they are related as product and process of use, the rationale set forth in paragraph 5 applies.

7. Groups I and VII represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, Group I is an array, while Group VII (a system) is interpreted as an apparatus. These products are completely different in form and effect and have completely different uses. Also, if it is argued that the invention of Group I is somehow related to the system of Group VII as product and process of use, it is noted that the array of Group I could be used in other processes, carried out by other apparatuses, such as a starting material for creation of further arrays (containing additional components made on an automatic synthesizer, for example). Also, see paragraph 8 below.

8. Groups IV and VII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process of Group IV could be carried out by hand (i.e. manual analysis of the array of samples).

9. The system of Group VII is not related to the methods of Groups II – V and VIII – X as the apparatus of Group VII does not appear to be able to be used to carry out the methods (processes) in Groups II – V and VIII – X (no disclosed relationship in the claims). However, if applicant were to argue that they are related as process(es) and apparatus for its practice, the rationale set forth in paragraph 8 applies.

10. Groups II – VI and VIII – X are different methods. The methods are different because they use different steps, require different reagents and/or will produce different results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the method of Group II is different from all of the methods of Groups III – VI and VIII – X because the method of Group II is a method of *preparing* an array, while the methods of Groups III – VI and VIII – X are methods of *using* arrays. These clearly represent different inventions.

11. Also, each of the methods of using an array (Groups III – VI and VIII – X) has a different end result as follows:

- Group III: end result – detecting at least one solid-form
- Group IV: end result – identifying an optimal solid-form
- Group V: end result – identifying sets of conditions and/or components to produce particular solid-forms
- Group VI: end result – identifying conditions and/or components that are compatible with one or more selected solid-forms
- Group VIII: end result – determining a set of processing parameters and/or components to inhibit the formation of a solid-form
- Group IX: end result – determining a set of processing parameters and/or components to dissolve or partially dissolve a solid-form

Group X: end result – identifying conditions and/or components which produce a compound-of interest or a diastereomeric derivative thereof in stereomerically enriched or conglomerate form

12. Moreover, Groups III, IV, V & IX appear to be different from Groups VI, VIII & X as the array used in the methods of Groups VI, VIII & X is not the same as the array used in Groups III, IV, V & IX (different reagents used in the methods). For example, in Group VI, the array comprises samples comprising the compound-of-interest in solid or dissolved form. In Group VIII, the array comprises samples comprising a solution of the compound-of-interest. In Group X, the array comprises samples comprising the compound-of-interest or a diastereomeric derivative thereof. See also paragraphs 5 and 6.

13. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Please note that even though some of these groups could be classified in the same class or subclass, this has no effect on the non-patent literature search. Different methods and products would require completely different searches in these databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

14. This application contains claims directed to patentably distinct species of the claimed invention for **Groups I - X**. Election is required as follows.

15. If applicant elects the invention of **Group I**, applicant is required to elect from the following patentably distinct species. Note: an election from EACH subgroup below is required. Claims 1-5, 12 and 18-21 are generic to this group.

Subgroup A: Type of difference (claim 6)

1. Amount or concentration of compound-of interest
2. Physical state of solid-form
3. Identity of one or more components
4. Amount or concentration of one or more components
5. Physical state of one or more components
6. pH

Subgroup B: Identity of compound-of-interest (claims 7-10)

First, an election from the "type" of compound-of-interest is required as follows:

1. Pharmaceutical; e.g. claims 8-10 ***
2. Alternative medicine
3. Dietary supplement
4. Nutraceutical
5. Sensory material
6. Agrochemical
7. Active component of a consumer formulation
8. Active component of an industrial formulation

Next, Applicant is required to elect, for purposes of search, a ***specific*** compound-of-interest. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure). ***Note that if species B1 (Pharmaceutical) is elected, then a specific type should be elected from those of claim 9 or 10 along with the election of a specific chemical structure.

Subgroup C: Identity of component (claim 11)

Applicant is required to elect, for purposes of search, a ***specific*** component from those set forth in claim 11. To avoid confusion, a single specific compound should be elected (i.e. specific chemical structure).

Subgroup D: Type of processing parameters (claim 13)

1. Adjusting temperature
2. Adjusting time
3. Adjusting pH
4. Adjusting amount or concentration of the compound-of interest
5. Adjusting amount or concentration of one or more components

6. Adding one or more additional components
7. Nucleation
8. Precipitation
9. Controlling evaporation of one or more components
10. Combinations (if a combination is elected, the specific combination of steps should be set forth)

Subgroup E: Type of solid-form (claims 14-17)

First, an election from the “type” of compound-of-interest is required as follows:

1. Amorphous
2. Crystalline

Next, Applicant is required to elect, for purposes of search, a specific form from those set forth in claim 15.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

16. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Not: an election from EACH subgroup below is required. Claims 22-25, 37 and 38 are generic to this group.

Subgroup A: Type of difference (claim 26)

1. Amount or concentration of compound-of interest
2. Physical state of solid-form
3. Identity of one or more components
4. Amount or concentration of one or more components
5. Physical state of one or more components
6. pH

Subgroup B: Identity of component (claim 27)

Applicant is required to elect, for purposes of search, a specific component from those set forth in claim 27. To avoid confusion, a single specific compound should be elected (i.e. specific chemical structure).

Subgroup C: Type of processing parameters (claim 28)

1. Adjusting temperature
2. Adjusting time
3. Adjusting pH
4. Adjusting amount or concentration of the compound-of interest
5. Adjusting amount or concentration of one or more components
6. Adding one or more additional components
7. Nucleation
8. Precipitation
9. Controlling evaporation of one or more components
10. Combinations (if a combination is elected, the specific combination of steps should be set forth)

Subgroup D: Type of solid-form (claims 29-32)

First, an election from the "type" of compound-of-interest is required as follows:

1. Amorphous
2. Crystalline

Next, Applicant is required to elect, for purposes of search, a specific form from those set forth in claim 30.

Subgroup E: Identity of compound-of-interest (claims 33-36)

First, an election from the "type" of compound-of-interest is required as follows:

1. Pharmaceutical; e.g. claims 34-36 ***
2. Alternative medicine
3. Dietary supplement
4. Nutraceutical
5. Sensory material
6. Agrochemical
7. Active component of a consumer formulation
8. Active component of an industrial formulation

Next, Applicant is required to elect, for purposes of search, a specific compound-of-interest. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure). ***Note that if species E1 (Pharmaceutical) is elected, then a specific type should be elected from those of claim 35 or 36 along with the election of a specific chemical structure.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements

needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

17. If applicant elects the invention of **Group III**, applicant is required to elect from the following patentably distinct species. Note: an election from EACH subgroup below is required. Claims 39-42, 58 and 59 are generic to this group.

Subgroup A: Type of difference (claim 43)

1. Amount or concentration of compound-of interest
2. Physical state of solid-form
3. Identity of one or more components
4. Amount or concentration of one or more components
5. Physical state of one or more components
6. pH

Subgroup B: Analysis method (claims 44-45)

Applicant is required to elect a specific method of analysis from those set forth in claim 45.

Subgroup C: Further analysis method (claims 46-47)

Applicant is required to elect a specific method of further analysis from those set forth in claims 46 or 47. *One* specific method should be elected.

Subgroup D: Identity of compound-of-interest (claims 48 and 55-57)

First, an election from the "type" of compound-of-interest is required as follows:

1. Pharmaceutical; e.g. claims 55-57 ***
2. Alternative medicine
3. Dietary supplement
4. Nutraceutical
5. Sensory material
6. Agrochemical
7. Active component of a consumer formulation
8. Active component of an industrial formulation

Next, Applicant is required to elect, for purposes of search, a ***specific*** compound-of-interest. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure). ***Note that if species D1 (Pharmaceutical) is elected, then a specific type should be elected from those of claim 56 or 57 along with the election of a specific chemical structure.

Subgroup E: Identity of component (claim 49)

Applicant is required to elect, for purposes of search, a specific component from those set forth in claim 49. To avoid confusion, a single specific compound should be elected (i.e. specific chemical structure).

Subgroup F: Type of processing parameters (claim 50)

1. Adjusting temperature
2. Adjusting time
3. Adjusting pH
4. Adjusting amount or concentration of the compound-of interest
5. Adjusting amount or concentration of one or more components
6. Adding one or more additional components
7. Nucleation
8. Precipitation
9. Controlling evaporation of one or more components
10. Combinations (if a combination is elected, the specific combination of steps should be set forth)

Subgroup G: Type of solid-form (claims 51-54)

First, an election from the "type" of compound-of-interest is required as follows:

1. Amorphous
2. Crystalline

Next, Applicant is required to elect, for purposes of search, a specific form from those set forth in claim 52.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

18. If applicant elects the invention of **Group IV**, applicant is required to elect from the following patentably distinct species. Note: an election from EACH subgroup below is required. Claims 60-64 and 81-85 are generic to this group.

Subgroup A: Type of difference (claim 65)

1. Amount or concentration of compound-of interest
2. Physical state of solid-form
3. Identity of one or more components

4. Amount or concentration of one or more components
5. Physical state of one or more components
6. pH

Subgroup B: Type of solid-form (claims 66-69)

First, an election from the “type” of compound-of-interest is required as follows:

1. Amorphous
2. Crystalline

Next, Applicant is required to elect, for purposes of search, a specific form from those set forth in claim 67.

Subgroup C: Analysis method (claims 70-71)

Applicant is required to elect a specific method of analysis from those set forth in claim 70 or 71.

Subgroup D: Identity of component (claim 72)

Applicant is required to elect, for purposes of search, a specific component from those set forth in claim 72. To avoid confusion, a single specific compound should be elected (i.e. specific chemical structure).

Subgroup E: Identity of compound-of-interest (claims 73 and 78-80)

First, an election from the “type” of compound-of-interest is required as follows:

1. Pharmaceutical; e.g. claims 78-80 ***
2. Alternative medicine
3. Dietary supplement
4. Nutraceutical
5. Sensory material
6. Agrochemical
7. Active component of a consumer formulation
8. Active component of an industrial formulation

Next, Applicant is required to elect, for purposes of search, a specific compound-of-interest. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure). ***Note that if species E1 (Pharmaceutical) is elected, then a specific type should be elected from those of claim 79 or 80 along with the election of a specific chemical structure.

Subgroup F: Type of processing parameters (claims 74-75)

1. Adjusting temperature
2. Adjusting time

3. Adjusting pH
4. Adjusting amount or concentration of the compound-of interest
5. Adjusting amount or concentration of one or more components
6. Adding one or more additional components
7. Nucleation
8. Precipitation
9. Controlling evaporation of one or more components
10. Combinations (if a combination is elected, the specific combination of steps should be set forth)

Subgroup G: Type of solid-form

1. Different polymorphs; e.g. claim 76
2. Different crystal habits; e.g. claim 77

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

19. If applicant elects the invention of **Group V**, applicant is required to elect from the following patentably distinct species. Note: an election from EACH subgroup below is required. Claims 86-90, 102 and 103 are generic to this group.

Subgroup A: Type of difference (claim 91)

1. Amount or concentration of compound-of interest
2. Physical state of solid-form
3. Identity of one or more components
4. Amount or concentration of one or more components
5. Physical state of one or more components
6. pH

Subgroup B: Type of processing parameters (claim 92)

1. Adjusting temperature
2. Adjusting time
3. Adjusting pH
4. Adjusting amount or concentration of the compound-of interest
5. Adjusting amount or concentration of one or more components
6. Adding one or more additional components
7. Nucleation
8. Precipitation

9. Controlling evaporation of one or more components
10. Combinations (if a combination is elected, the specific combination of steps should be set forth)

Subgroup C: Type of solid-form (claims 93-96)

First, an election from the “type” of compound-of-interest is required as follows:

1. Amorphous
2. Crystalline

Next, Applicant is required to elect, for purposes of search, a specific form from those set forth in claim 94.

Subgroup D: Identity of compound-of-interest (claims 97 and 99-101)

First, an election from the “type” of compound-of-interest is required as follows:

1. Pharmaceutical; e.g. claims 99-101 ***
2. Alternative medicine
3. Dietary supplement
4. Nutraceutical
5. Sensory material
6. Agrochemical
7. Active component of a consumer formulation
8. Active component of an industrial formulation

Next, Applicant is required to elect, for purposes of search, a specific compound-of-interest. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure). ***Note that if species D1 (Pharmaceutical) is elected, then a specific type should be elected from those of claim 100 or 101 along with the election of a specific chemical structure.

Subgroup E: Identity of component (claim 98)

Applicant is required to elect, for purposes of search, a specific component from those set forth in claim 98. To avoid confusion, a single specific compound should be elected (i.e. specific chemical structure).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

20. If applicant elects the invention of **Group VI**, applicant is required to elect from the following patentably distinct species. Note: an election from EACH subgroup below is required. Claims 104-107, 116 and 117 are generic to this group.

Subgroup A: Type of difference (claim 108)

1. Amount or concentration of compound-of interest
2. Physical state of solid-form
3. Identity of one or more components
4. Amount or concentration of one or more components
5. Physical state of one or more components
6. pH

Subgroup B: Type of processing parameters (claim 109)

1. Adjusting temperature
2. Adjusting time
3. Adjusting pH
4. Adjusting amount or concentration of the compound-of interest
5. Adjusting amount or concentration of one or more components
6. Adding one or more additional components
7. Nucleation
8. Precipitation
9. Controlling evaporation of one or more components
10. Combinations (if a combination is elected, the specific combination of steps should be set forth)

Subgroup C: Type of solid-form (claims 110)

Applicant is required to elect, for purposes of search, a specific form from those set forth in claim 110.

Subgroup D: Identity of compound-of-interest (claims 111 and 113-115)

First, an election from the "type" of compound-of-interest is required as follows:

1. Pharmaceutical; e.g. claims 113-115 ***
2. Alternative medicine
3. Dietary supplement
4. Nutraceutical
5. Sensory material
6. Agrochemical
7. Active component of a consumer formulation
8. Active component of an industrial formulation

Next, Applicant is required to elect, for purposes of search, a specific compound-of-interest. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure). ***Note that if species D1 (Pharmaceutical) is elected, then a specific type should be elected from those of claim 114 or 115 along with the election of a specific chemical structure.

Subgroup E: Identity of component (claim 112)

Applicant is required to elect, for purposes of search, a specific component from those set forth in claim 112. To avoid confusion, a single specific compound should be elected (i.e. specific chemical structure).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

21. If applicant elects the invention of Group VII, applicant is required to elect from the following patentably distinct species. Note: an election from EACH subgroup below is required. Claims 118-123 are generic to this group.

Subgroup A: Identity of detector (claim 124)

Applicant is required to elect, for purposes of search, a specific detector from those set forth in claim 124.

Subgroup B: Identity of analyzer (claims 125-127)

Applicant is required to elect, for purposes of search, a specific analyzer from those set forth in claim 126 or 127.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

22. If applicant elects the invention of **Group VIII**, applicant is required to elect from the following patentably distinct species. Note: an election from EACH subgroup below is required. Claims 128-131, 139 and 140 are generic to this group.

Subgroup A: Type of difference (claim 132)

1. Amount or concentration of compound-of interest
2. Physical state of solid-form
3. Identity of one or more components
4. Amount or concentration of one or more components
5. Physical state of one or more components
6. pH

Subgroup B: Type of processing parameters (claim 133)

1. Adjusting temperature
2. Adjusting time
3. Adjusting pH
4. Adjusting amount or concentration of the compound-of interest
5. Adjusting amount or concentration of one or more components
6. Adding one or more additional components
7. Nucleation
8. Precipitation
9. Controlling evaporation of one or more components
10. Combinations (if a combination is elected, the specific combination of steps should be set forth)

Subgroup C: Identity of component (claim 134)

Applicant is required to elect, for purposes of search, a ***specific*** component from those set forth in claim 134. To avoid confusion, a single specific compound should be elected (i.e. specific chemical structure).

Subgroup D: Identity of compound-of-interest (claims 135-138)

First, an election from the "type" of compound-of-interest is required as follows:

1. Pharmaceutical; e.g. claims 136-138 ***
2. Alternative medicine
3. Dietary supplement
4. Nutraceutical
5. Sensory material
6. Agrochemical
7. Active component of a consumer formulation
8. Active component of an industrial formulation

Next, Applicant is required to elect, for purposes of search, a specific compound-of-interest. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure). ***Note that if species D1 (Pharmaceutical) is elected, then a specific type should be elected from those of claim 137 or 138 along with the election of a specific chemical structure.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

23. If applicant elects the invention of Group IX, applicant is required to elect from the following patentably distinct species. Note: an election from EACH subgroup below is required. Claims 141-144 and 152 are generic to this group.

Subgroup A: Type of difference (claim 145)

1. Amount or concentration of compound-of interest
2. Physical state of solid-form
3. Identity of one or more components
4. Amount or concentration of one or more components
5. Physical state of one or more components
6. pH

Subgroup B: Type of processing parameters (claim 146)

1. Adjusting temperature
2. Adjusting time
3. Adjusting pH
4. Adjusting amount or concentration of the compound-of interest
5. Adjusting amount or concentration of one or more components
6. Adding one or more additional components
7. Nucleation
8. Precipitation
9. Controlling evaporation of one or more components
10. Combinations (if a combination is elected, the specific combination of steps should be set forth)

Subgroup C: Identity of component (claim 147)

Applicant is required to elect, for purposes of search, a *specific* component from those set forth in claim 147. To avoid confusion, a single specific compound should be elected (i.e. specific chemical structure).

Subgroup D: Identity of compound-of-interest (claims 148-151)

First, an election from the "type" of compound-of-interest is required as follows:

1. Pharmaceutical; e.g. claims 149-151 ***
2. Alternative medicine
3. Dietary supplement
4. Nutraceutical
5. Sensory material
6. Agrochemical
7. Active component of a consumer formulation
8. Active component of an industrial formulation

Next, Applicant is required to elect, for purposes of search, a *specific* compound-of-interest. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure). ***Note that if species D1 (Pharmaceutical) is elected, then a specific type should be elected from those of claim 150 or 151 along with the election of a specific chemical structure.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

24. If applicant elects the invention of **Group X**, applicant is required to elect from the following patentably distinct species. Note: an election from EACH subgroup below is required. Claims 153, 156-158 and 167-169 are generic to this group.

Subgroup A: Type of samples

1. Compound-of-interest in enantiomerically enriched form; claim 154
2. Diastereomeric derivative in diastereomerically enriched form; claim 155

Subgroup B: Type of difference (claim 159)

1. Amount or concentration of compound-of interest

2. Physical state of solid-form
3. Identity of one or more components
4. Amount or concentration of one or more components
5. Physical state of one or more components
6. pH

Subgroup C: Type of processing parameters (claim 160)

1. Adjusting temperature
2. Adjusting time
3. Adjusting pH
4. Adjusting amount or concentration of the compound-of interest
5. Adjusting amount or concentration of one or more components
6. Adding one or more additional components
7. Nucleation
8. Precipitation
9. Controlling evaporation of one or more components
10. Combinations (if a combination is elected, the specific combination of steps should be set forth)

Subgroup D: Identity of compound-of-interest (claims 161 and 163-165)

First, an election from the “type” of compound-of-interest is required as follows:

1. Pharmaceutical; e.g. claims 163-165 ***
2. Alternative medicine
3. Dietary supplement
4. Nutraceutical
5. Sensory material
6. Agrochemical
7. Active component of a consumer formulation
8. Active component of an industrial formulation

Next, Applicant is required to elect, for purposes of search, a ***specific*** compound-of-interest. To avoid confusion, a specific compound should be elected (i.e. specific chemical structure). ***Note that if species D1 (Pharmaceutical) is elected, then a specific type should be elected from those of claim 164 or 165 along with the election of a specific chemical structure.

Subgroup E: Identity of component (claim 162)

Applicant is required to elect, for purposes of search, a ***specific*** component from those set forth in claim 162. To avoid confusion, a single specific compound should be elected (i.e. specific chemical structure).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

25. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

26. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

27. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

28. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

29. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

30. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

31. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
March 20, 2002



MAURIE E. GARCIA, PH.D.
PATENT EXAMINER



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